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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,303	01/26/2007	Hiromi Matsuzaki	P30093	5121

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EXAMINER	
WOLF, MEGAN YARNALL	
ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
11/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/596,303	MATSUZAKI ET AL.	
	Examiner	Art Unit	
	Megan Wolf	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,14 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,14,and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/09 has been entered.

Response to Arguments

2. Applicant's arguments filed 10/19/09 have been fully considered but they are not persuasive. Applicant argues that Carrison, Kim, Tofighi, and Shimp fail to disclose *how* the bone replacement material is packed into the cavity of the bone defective part using the cylindrical member as recited in the claimed invention. However, the claims are directed to a bone replacement material and not the method of using the material. How the device is packed into a cavity is not germane to the issue of patentability of the device itself. Carrison, Kim, Tofighi, and Shimp disclose the structural limitations of the actual bone replacement material and therefore the bone replacement material disclosed by the prior art is capable of being packed into a cavity of the bone defective part using a cylindrical member having a hollow passage, being introduced and packed into a cavity of the bone defective part using a cylindrical member in the claimed arrangement wherein the inclined surfaces of the pellets are facing, and being pushed out in various directions from the cylindrical member. Applicant further argues that

Carrison teaches away from the intended use of the invention but since the claims are directed to the bone replacement material itself and not the method of implanting the material, the means by which material are implanted is minimally relevant to the claimed subject matter and the material only needs to be capable of being used in the claimed manner. Carrison does not teach away from the invention simply because specific means of introducing the pellets into a bone space are disclosed that differ from the intended use of the device. In order for a reference to "teach away," it must criticize, discredit, or discourage the solution claimed (See also MPEP 2145(X)(D)(1)).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8, 10, 14, and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 lines 11-13 state that “the bone replacement material is in a state such that a number of pellets of the bone replacement material are introduced into a cavity of the bone defective part and are aggregated therein". This limitation renders the claim indefinite because it positively recites a method step but the invention is directed to a bone replacement material not a method of implanting the material.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-8, 10, 14, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrison et al. 2005/0038517 in view of Shimp 2004/0052829 in further view of Kim et al. 5,645,596 and in further in view of Tofighi et al. 2003/0120351.

Re claim 1, Carrison discloses the invention substantially as claimed including a bone replacement material to be used by being packed into a bone defective part, wherein the bone replacement material is a rigid biocompatible material (par.45) and is formed into a pellet wherein the pellet has a roughly polyhedral shape and is defined by a plurality of surfaces including a pair of opposite, non-parallel surfaces, one of the opposite, non-parallel surfaces being inclined at a predetermined angle with respect to the other of the opposite, non-parallel surfaces (fig.3), wherein the bone replacement material is in a state such that a number of pellets of the bone replacement material are capable of being introduced into a cavity of the bone defective part using a cylindrical member having hollow passage and aggregated therein. The bone replacement material is also capable of being used in the manner claimed wherein each pellet is inserted into the hollow passage of the cylindrical member such that the inclined surface of the pellet faces the inclined surface of an adjacent pellet and the pellets are pushed out in various directions. Carrison discloses porous pellets that have a longest edge, a shortest edge, and a volume, but does not disclose the specific size of these dimensions wherein the longest edge is in the range of 5-10 mm, the shortest edge is in

the range of 2-5 mm and the volume is in the range of 13 to 239 mm^3 or that the material consists essentially of calcium phosphate.

Shimp teaches bone replacement pellets, in the same field of endeavor, wherein the pellets are formed of porous calcium phosphate for the purpose of resisting deformation or fracture under the physiologic loads normally experienced at the repair site (pars.28-30), and wherein the pellets can vary in size but are preferably up to about 4mm (yielding a volume of about $64mm^3$), for the purpose of providing an injectable load bearing support at the repair site (par.10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use calcium phosphate for the implant material in order to provide an implant material that resists deformation or fracture under the physiologic loads normally experienced at the repair site. It would have been further obvious to specify the claimed size ranges for the pellets of Carrison as this size is best suited for injecting bone replacement material into a bone defect in the spine as taught by Shimp and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). While Carrison in view of Shimp discloses porous calcium phosphate pellets, Carrison in view of Shimp does not specifically disclose that the porosity is equal to or less than 75% and that the collapsing strength is equal to more than 15Mpa.

Kim teaches a vertebral prosthesis, in the same field of endeavor, wherein calcium phosphate is used as an implant material for the purpose of its spontaneous

adhesion to the associated vertebrae, and wherein the porosity of the calcium phosphate is preferably between 30 and 45% for the purpose of simultaneously providing mechanical strength and promoting tissue ingrowth (col.4, ll.32-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use calcium phosphate with a porosity of less than 75% as taught by Kim for the vertebral implants of Carrison in view of Shimp in order to allow for tissue ingrowth for anchoring the implant while maintaining mechanical strength to resist compression forces. As Kim discloses the claimed porosity as well as the Ca/P ratio claimed in claim 19, one would assume that the collapsing strength of the calcium phosphate compound of Kim is equal to or more than 15 MPa. Still, Carrison in view of Shimp in further view of Kim does not specifically state that the collapsing strength of the calcium phosphate based compound is 15MPa or more.

Tofighi teaches a calcium phosphate compound for use in an implant, in the same field of endeavor, wherein the final porous calcium phosphate compound has a compression strength of greater than 20MPa for the purpose of being useful as a weight bearing implant material (par.56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to specify that the calcium phosphate compound of Carrison in view of Shimp in further view of Kim have a collapsing strength greater than 15Mpa in order to provide a material that is strong enough for use as an implant that is required to bear weight as taught by Tofighi.

Re claims 2-4, and 10, see Carrison fig.3.

Re claims 5-8, while Carrison does not specifically disclose that the implant is either a pentahedral, cylindrical, or a triangular prism shape, these shapes are simply a matter of design choice and as it has been held that changes in shape are a matter of design choice, which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B).

Re claims 16, 20, and 21, see Carrison figs. 13-18. Note that while Carrison does not disclose that the implants are inserted into the hollow passage of a cylindrical member such that the inclined surface of a pellet faces the inclined surface of an adjacent pellet, because of their shape shown in fig.3, the pellets of Carrison are capable of such use.

Re claim 19, see Kim col.4, ll.25-30.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738